EXHIBIT 24

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KITCHEN WINNERS NY INC.,
Plaintiff,

vs.

CASE NO.
22-CV-05276-PAE

ROCK FINTEK LLC,
Defendant.

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ROCK FINTEK LLC,
Third-Party
Plaintiff and
Counterclaimant,

vs.

KITCHEN WINNERS NY INC.,
Counterclaim
Defendant,

and

JNS CAPITAL HOLDINGS LLC, JOEL STERN, HERSHEY WEINER, JOSEPH MENDLOWITZ, ADORAMA, INC.,
Third-Party
Defendants.

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DEPOSITION OF

ALAN SCHWARTZ

Tuesday, February 13, 2024

12:11 P.M.

Videoconference

Reported By John Sheffield, Commission No. 01SH6435698

Job No. 00048635

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INDEX OF EXAMINATION

WITNESS: ALAN SCHWARTZ

INDEX TO EXHIBITS

(Exhibit 1 was attached to the original transcript. Exhibits 3 through 4 and 6 through 8 were retained.)

(On the record at 12:11 P.M.)

THE COURT REPORTER: We are here today for the purposes of recording the deposition of Dr. (sic) Alan Schwartz taken by Plaintiff in the matter of Kitchen Winners, New York, Inc. v. Rock FinTek, LLC, case number 22-CV-05276-PAE in the District Court, Southern District of New York.

Counsel will now state their appearances.

MR. RAKHUNOV: Good -- good afternoon. My name is Phillip Rakhunov with Pollack Solomon Duffy. I represent Rock FinTek, LLC.

MR. SPERBER: Good afternoon. My name is Alexander Sperber of Lipsius-BenHaim. I represent Kitchen Winners, Adorama, and Joseph Mendlowitz.

MR. FRISCH: Good afternoon. Avram Frisch, the law office of Avram E. Frisch, and I represent JNS Capital Holdings and Joel Stern, third-party defendants.

THE COURT REPORTER: Thank you. I will now swear in the witness.

Mr. -- Dr. Allen Schwartz, do you swear --

MR. SCHWARTZ: No. It's -- it's Mr.

THE COURT REPORTER: Okay.

ALAN SCHWARTZ,

having first been duly sworn, testified as follows:

THE COURT REPORTER: Thank you, sir.

You may now begin.

EXAMINATION

BY MR. RAKHUNOV:

Q. Good afternoon, Mr. Schwartz. We met briefly off the record. My name is Phillip Rakhunov. I represent Rock FinTek.

When -- when is the last time you were deposed in any case?

A. Let me see. I have to refresh my memory. It -- it was probably about a year or two ago.

Q. So I -- I assume you're familiar with the process. I'll -- I will ask you questions. You -- you will answer them to the best of your ability. We'll try not to speak over each other so the court reporter can take down a clean record. Your attorneys may object from time to time, but unless you're instructed not to answer, please do. If you do not understand any of my questions, let me know and I will do my best to clarify. If you answer, I will assume you understood my question.

Is that fair?

A. That's fair. No problem with that.

Q. All right. And any reasons such as medications, or any other reason that you're not able

to testify clearly and truthfully today?

A. Under no medications.

Q. Do you have any notes or memory aids in front of you to assist in -- with your testimony?

A. Nope.

Q. Anyone in the room with you today?

A. Nope.

Q. And anyone communicating with you via any device during this deposition?

A. Nope.

MR. RAKHUNOV: You have before you, or you should have before you, Exhibit 1, which is an expert disclosure that we were provided by your counsel in this case. It's a 73-page document consisting of the caption, Expert Disclosure, and then your expert rebuttal report with exhibits.

(EXHIBIT 1 MARKED FOR IDENTIFICATION)

BY MR. RAKHUNOV:

Q. Do you have that before you, sir?

A. I do.

Q. So first, I -- I'd like to direct your attention to your CV, which is at the end of the report. It is page 68 of the PDF document. Let -- let me know when you get there.

A. Okay.

Q. So is this -- oh, sorry. Is -- is the CV attached with your expert disclosure in Exhibit 1 a complete and accurate and updated description of your experiences and qualifications?

A. As far as I can tell, yes.

Q. So you are executive vice president with MDI Consultants, correct?

A. Well, actually, there has been a change consensus. I am now president of MDI Consultants.

Q. As -- as of when?

A. Let's see, about beginning of February.

Q. What does MDI Consultants do?

A. MDI is a consulting company specializing in U.S. Food and Drug regulations. We consult to the manufacturers of medical devices, pharmaceuticals, and foods, as well as nutritional supplements on all aspects of FDA compliance.

Q. Have you, in your work with MDI, ever consulted to a manufacturer of -- of gloves, medical gloves?

A. Yes, I have.

Q. Have you consulted the glove manufacturers located overseas, including China?

A. Correct.

Q. Have you provided any consulting services to

a company known as Global Tooling Services?

A. Not that I could recall. I don't think so.

Q. Have you ever provided consulting services to any company that ever manufactured gloves under the brand name Medcare, M-E-D-C-A-R-E?

A. Not that I can recall. I don't think so.

Q. Okay. And do you recall having ever worked with an individual by the name of Anna Grinvald, G-R-I-N-V-A-L-D?

A. Not that I can recall.

Q. Approximately how many glove manufacturers have you consulted to in your career? And I'm talking about medical -- I'm -- I'm sorry.

Just to clarify, medical gloves as opposed to food service or other gloves?

A. I would say in the realm of 30 to 50 companies.

Q. Have you ever provided consulting services outside of this lawsuit to any importers of medical gloves who were not the manufacturer?

A. Yes.

Q. And did -- how many -- how many such importers have you provided services to?

A. I would say a dozen at least.

Q. And have you provided any such services

during -- so since the COVID-19 pandemic broke out?

MR. SPERBER: Objection to form. Can you clarify when you say, since? Is that meaning --

MR. RAKHUNOV: Sure.

MR. SPERBER: -- the beginning or since the end?

BY MR. RAKHUNOV:

Q. How about -- how about since the beginning of March -- since -- since the beginning of 2020 through the present?

A. Yes.

Q. Are you able to identify those clients?

A. I -- right. I mean, I would be able to, but I don't have them off the top of my head, because I deal with a lot of companies over the years.

Q. Can you identify any of the importers of gloves to whom you provided consulting services?

A. You know what, I -- I do not have a good memory for names.

Q. But you would be able to obtain that information if you looked through your records, correct?

A. Yes, I would.

Q. What type of consulting services have you provided to importers of medical gloves into the U.S.

since January 1st, 2020, through the present?

A. Some importers like to get their own 510(k), which is a pre-market notification for them to be able to import medical gloves into the United States. I help them with the 510(k). I help them registering with the FDA as an initial importer, which is a requirement if they are the initial importer for foreign manufacturers. I help them with their quality system of what is expected of them as an initial importer. And I help them identify the companies, whether they have a 510(k), and if they are registered.

Q. What entails having -- getting an importer registered with a 510(k) number?

A. A -- an importer would need to submit an application to the FDA on the technical aspects of the product or the -- the gloves, have all the necessary testing and labeling, and we would prepare and submit the application to the FDA.

Q. And were any of the gloves, with respect to which you provided services, nitrile examination gloves?

A. Yes.

Q. Okay. What -- what are the requirements to obtain a 510(k) certification to import nitrile examination gloves into the United States?

A. Well, for nitrile gloves, like for any gloves, the -- they have to do biocompatibility testing on sensitivity and irritation. They have to do spec testing to show that it meets the standards. And -- and they would have to submit that information to the FDA as part of an application.

Q. When you say they have to do spec testing to meet the standards, what standards specifically are you referring to?

A. There are ASTM standards. I do not know the number offhand.

Q. Does D6319 sound familiar?

A. It could be, yes.

Q. And -- and you -- you mentioned biocompatibility testing. What does that mean?

A. Well, because gloves are -- come in contact with the skin, the FDA wants to make sure that the gloves are found to be safe for their use. So they have to do biocompatibility, it's irritation and sensitivity testing, which is usually animal testing, to show that the gloves are safe to be handled.

Q. And -- and when you -- I'm sorry, give me one second. I'm actually e-mailing -- it goes slightly out of order, but I'm going to e-mail another exhibit to Mr. Sperber that hopefully he can forward to you.

When you mention certain ASTM testing for nitrile medical examination gloves, did the ASTM standards vary, be -- from -- you know, from glove to glove, or is there one overall set of standards that would apply to all nitrile examination gloves in order to obtain a 510(k) number?

A. Since I'm not a lab specialist or a chemist, I am not sure if there would be multiple standards that would have to -- that would be available. There might be. But the FDA allows if there -- if there is a recognized standard, the FDA allows you to use that standard to get the 510(k). Are there multiple standards for nitrile gloves? I am not sure. I could not answer that.

Q. And if -- and in your experience, is a glove importer able to rely on an existing 510(k) number that, for example, a glove manufacturer in China had previously obtained?

A. If a foreign manufacturer has a 510(k), is registered and listed, the products are listed with the FDA, they're allowed to export, and an importer is allowed to accept those products. And the FDA would normally green -- what's called green ticket those products so the importer could take ownership of them.

Q. And if a particular and -- and if -- if a

particular 510(k) number is used to import gloves, then the importer -- let -- let me rephrase that.

MR. RAKHUNOV: You know, I actually -- Alex, have you received my e-mail yet?

MR. SPERBER: Yes. I forwarded it to Mr. Schwartz.

MR. RAKHUNOV: Okay.

Yeah, Mr. Schwartz, there -- there should be an e-mail that you received from Counsel that will have an attachment that's labeled Exhibit 7. I know we're going a little bit out of order, but please let me know when --

(EXHIBIT 7 MARKED FOR IDENTIFICATION)

THE WITNESS: I -- I have it.

BY MR. RAKHUNOV:

Q. You have it?

A. I received it.

Q. Okay. Great. Do you have that open?

A. Yes.

Q. Okay. So this is a letter dated March 9th, 2016, regarding -- in the first line of the subject, it says, K-152712. Do you see that?

A. Yes, I do.

Q. Does this letter look familiar to you in terms of its format and contents, generally?

A. Yes, it does.

Q. Okay. What do you -- do you understand what this letter is?

A. This is a -- an FDA clearance letter for the 510(k) that was submitted to the FDA by that company.

Q. And this specific document, have you reviewed this document in connection with your work in this case?

A. No.

Q. Okay. So this is the first time you're seeing this specific document, correct?

A. Correct.

Q. And a -- a manufacturer company that obtains -- that obtained this pre-market approval letter, what does this letter authorize or allow that manufacturer to do?

A. All right. First of all, I just want to clarify, it's not an approval. It's a pre-market clearance.

Q. What's the difference?

A. 510(k)s --the FDA does not approve a 510(k). A 510(k) is showing how your product is substantially equivalent to a product that is already -- have a 510(k). So they are clearing your 510(k) stating that they have found it to be substantially equivalent to

the 510(k) that you submitted, or to a product that's already on the market.

A -- an approval is given to a PMA or de novo, those who have to prove safety and efficacy, and there is no substantially equivalent. So a 510(k) is cleared, not approved.

Q. I appreciate the clarification. So this clearance letter -- is it fair to say that this clearance letter entitles the holder of the 510(k) number to import nitrile powder-free patient examination gloves, blue color?

A. That is correct.

Q. And if you turn to Page 5 of this Exhibit 7, Paragraph -- Paragraph 6, does -- what -- what does Paragraph 6 describe?

A. Let me see. Page 5. Let me see what -- Page 5. I'm on Page 7. Hold on.

Q. Yeah. It -- it's Page 5 of the PDF, not -- there's no -- it's numbered Page 2 out of 4, actually, of --

A. Yeah. Two out of --

Q. -- Section C.

A. Do you want me -- Number 6 you wanted me to look at?

Q. Yes, sir.

A. All right. So that is a -- let's see. Standard. That is their summary of the technology -- tech characteristics of the device that they're looking 510(k) --

Q. And what is that -- what -- what -- what is the significance of the description of the -- the table in Section 6?

A. Well, the company is supposed to outline the characteristics of their device, what standards they use, and the -- what the results of those tests were. So in this case, they did a dimension test, the -- well, first of all, they outlined that it's nitrile, powder-free examination gloves, blue color, non-sterile. And they tested it for dimensions using an ASTM standard D, as in David, 6319-10, and they found that it meets those performance standards.

Then they did a test for physical properties. Again, ASTM standard D6319-10, and they said it met the performance property testing. Then they did a test for freedom from pinholes, and that -- they said they followed 21CFR820, and they found that it meets those requirements. They did a powder residual test using ASTM standards, D, again David, 6319-10 and D, as in David, 6124-06 reapproved 2011, and they said it met those requirements, less than two

milligrams per whole -- glove -- sorry, per glove.

And again, finally, they did the biocompatibility studies, which we discussed. They did a primary skin irritation in rabbits, ISO standard 10993-10, third edition, 2 -- 2010-08-01. I guess that's the date of that standard. And they said under the conditions of the study, the subject's devices is non-irritating. And they also did, under biocompatibility, their dermal sensitivity test -- testing in guinea pigs. And it's ISO standard 10993-10, third edition, 2010-08-01. And they said under the conditions of the study, the subject's devices is not -- is not a sensitizer.

Q. And -- and then if you turn to the next page, looking at the chart in Section 9, and -- you know, do you -- take -- take as much time as you need to review it. I -- I don't think we need to read the -- the whole thing into the record, but is it fair that -- that Section 9 contains a detailed comparison of the predicate device in -- in the second column compared to the device for which clearance is being sought in this letter with respect to the product names, size, intent for use, and various specifications and properties?

A. Yeah. This is a very common substantially equivalent chart that we use for all our 510(k)s.

And doing a quick review, it looks like they did a -- a good comparison and found them to be equal -- either the same or found them to be substantially equivalent.

Q. So is it fair to say that any -- any manufacturer or importer or seller of these gloves under the 510(k) number issued in this letter is required to provide gloves that meet the specifications described in this clearance letter?

MR. SPERBER: Objection to the form.

You -- you can answer.

THE WITNESS: The company is stating that these are the requirements and specifications of their gloves, and those gloves that they ship are supposed to meet these specifications.

BY MR. RAKHUNOV:

Q. And -- and just to be clear, a -- I -- I'm sorry if I'm asking you this again, but I -- I just don't remember if I asked you this exactly.

If a trader of gloves, like for example, Kitchen Winners, a party to this case, is -- is -- is telling a buyer that they're providing gloves under the 510(k) number set forth in this letter, again, then those gloves would be expected to meet the specifications described herein?

MR. SPERBER: Objection to the form.

THE WITNESS: Can I answer it?

MR. SPERBER: Yes.

BY MR. RAKHUNOV:

Q. Yes.

A. Well, an importer could only go with what the manufacturer is supplying. So if the -- if they are purchasing gloves that are nitrile gloves that had a 510(k), they're expecting those gloves to meet that specification. But they normally don't do any testing on the gloves once they come in.

They're -- the -- the responsibility of the specification is going to fall on the manufacturer, ultimately.

Q. What -- what do you mean by that?

A. Well, if -- if the FDA were to sample the gloves before they came in, if there was any problems, the gloves would be stopped at the port. If the gloves are found to have a problem after they're brought into the country, they would go to -- to the importer, find out what was going on, find out who the supplier was. Because sometimes the boxes might have a brand name that is -- that doesn't relate to the manufacturer. And then they would go back to the manufacturer and see what went on and what the problems -- of why these

products are not meeting specifications.

Q. So in -- in other words, is it accurate to say that if -- if one is a buyer of gloves with a certain 510(k) number -- well, let -- let me ask you to be more specific.

If -- if one is a buyer of gloves with the 510(k) number listed in this letter, that company or individual would expect those gloves to meet the specifications herein. Is that -- is that what you're saying?

A. That's correct. I think I lost your sound.

Q. No. No. I -- I -- I actually was just taking a pause.

All right. Well, we can -- we can put --

A. I saw your lips move. That's why I thought --

Q. We can put that as -- maybe there's a little lag there. Let -- let's put Exhibit 7 aside for the moment, and -- well, let me actually ask you one question.

So if -- if -- if a product is being sold as having a 510(k) certification, does that mean that the FDA would have issued either an approval or a clearance letter by the time the product is being sold?

A. Well, first of all, again, the FDA gives a

clearance letter, not a certification. So you get a clearance letter on your 510(k). Before you could export, the -- the company needs the 510(k) because they're going to have to register with the FDA.

They're going to have to list the device. If the device requires a 510(k), they're going to have to have the 510(k) number on the device listed. Without that, they couldn't -- they -- I mean, not that it's guaranteed it wouldn't get through. If the FDA caught it, it would be stopped at the border, that they would not be able to be import -- export their product into the U.S.

Q. And how does the FDA -- I -- I guess the FDA, or a customs agent, know whether or not a given product has 510(k) clearance at the time of import?

A. Every shipment, medical device shipment, goes through customs. If it's a medical device, it's sent to the FDA for green ticketing or rejection. The FDA then could go into their database, look at the company, look at the 510(k) number, look at their registration, and see are they registered, is the device listed, does it have a 510(k)? If any of those are not there, the FDA would put a hold on it. If any of those are there, the FDA usually, unless they find something suspicious or some problem, they would green

ticket it and let it into the country.

Q. And does the FDA actually -- or customs agent, actually open up, for example, boxes of gloves and do any physical ASTM or other testing to check if those products actually conform to the specifications in the FDA clearance?

A. Not usually. There are just too many products coming into the country. Unless they're doing a specific sampling program, or they are suspicious of a problem, usually the products are released into the country without exam -- without exam.

Q. Is it possible that -- for products to get into the country that have -- that were manufactured at a factory that does not have a 510(k) certification?

A. Unfortunately, yes.

Q. So for example, if a container of gloves has some cartons that are -- well, withdraw.

Are you -- are you aware of product code specifications associated with FDA 510(k) certifications -- or sorry, clearances?

A. No. No. The product code --

Q. Well, let -- let --

A. With the 510(k) -- if you're talking about the FDA three -- three letter code has nothing to do --

Q. Yes.

A. -- with the -- of -- with the 510(k).

Q. So -- and if you look at Page 1 of Exhibit 7, do you see LZA product code?

A. Yes, I do.

Q. Well, do you know what that refers to?

A. Well, I'm not sure if that is the right code. It -- I guess it's the right code, because the FDA put it down, but that is a code for a patient examination glove.

Q. Got it. In your in your CV you describe something as QSR/CGMP. What does that mean?

A. Yeah. All right. QSR stands for Quality System Regulation, and then the FDA does /C, means current, G is good, M is manufacturing, and P is practices.

Q. Do you --

A. This is for the regulations dealing with manufacturing of medical devices, what companies are required to be in compliance with.

THE COURT REPORTER: Could you please repeat the -- the name -- the name -- the Q? Starting with the Q?

THE WITNESS: Q stands for quality, S is system, R is regulations. The C is for current, C-U-R-R-E-N-T, good manufacturing practices.

THE COURT REPORTER: Thank you for that.

BY MR. RAKHUNOV:

Q. So let -- let me actually go back for a moment. So you -- you -- you testified a few minutes ago that some importers like to get their own 510(k) number?

A. That is correct.

Q. So you know, in a situation, like -- like the one we have here, where -- where a non-manufacturer is importing medical gloves into the United States, what steps would that importer take to get their own 510(k) number rather than rely on the one provided by the manufacturer?

A. All right. Usually, we recommend if a company is going to be doing a lot of importing and wants to control the product and have their own product, they get a 510(k). Many times, they don't want to rely on one manufacturer supplying them the product, so they want to have more control.

They would have to find or -- or get product -- they could -- they could use the product that they're importing, get all the testing done under their name, and submit the application showing they're substantially equivalent to the device that's already being imported. And then they would be considered a

specification developer and an importer. And then they would find a contract manufacturer to make the gloves for them.

Does that make sense? Is that clear?

Q. It -- it does make sense. So they would have to demonstrate similar type of bioequivalency as a manufacturer would for a pre-existing product, or compared to a pre-existing product?

A. Correct. And a lot of them might actually take the product they're importing and have that tested and claiming these are the specs they're going to make. The FDA approves -- I mean, a company could move from one manufacturer to another as long as the manufacturer meets the same specifications for the finished product.

Q. And -- and by the way, in your experience, what -- what types of nitrile gloves -- nitrile rubber gloves are approved for medical uses?

A. Ones that would pass that ASCM -- ASTM testing. I -- I'm not sure what that question means. If there are multiple nitrile -- I think there are different colored nitrile gloves, but I think they all have to pass that standard.

Q. Are you aware of any product code or any medical gloves, nitrile gloves, described as protection gloves as opposed to --

A. Well, there are --

Q. As opposed to --

A. Yeah. They -- they're -- they're -- I'm not sure if they're nitrile. There might be nitrile gloves that might be used for -- for various chemicals, like if they're doing chemotherapy or things like that. They might be called protection gloves.

Now, under the PP -- PPP, everything was a protection glove. So I'm not sure if that's what you're looking for. I'm not sure what you're -- exactly what you're looking for here.

Q. What's PPP?

A. Personal protection -- well, the personal product protection. These were all the stuff under the COVID -- oh, PPE, personal --

Q. I'm sorry. PPE. Okay. But that -- that's not -- but that has nothing to do with the 510(k) registration, correct?

A. No. You would need your -- well, at the time, every -- a lot of stuff was passing through because of the Emergency Use Act. But the only other gloves that might be under protection are chemical gloves that are -- that are -- are rated for different chemicals.

Q. Would that have a separate product code from

-- different from LZA that we looked at a moment ago?

A. Yes. They would.

Q. And it would have to have a different 510(k) clearance or registration from a nitrile examination glove, correct?

A. Correct.

Q. Has -- have you been retained in this case by Kitchen Winners or -- or any other parties to provide any expert opinion on whether the gloves at issue were, in fact, 510(k) registered gloves, one way or another?

A. No.

Q. Let me turn back to your CV. Let's see. There is a number of bullet points on the first page. And bullet point 3 says, "audited over 400 medical device, pharmaceutical manufacturers, and food companies worldwide for FDA compliance, sterile and not sterile devices." Do you see that?

A. Yes.

Q. Can -- can you describe what type -- well, let -- let me actually try to narrow it down. Were any of these audits involving companies that either manufactured or sold nitrile medical gloves?

A. Probably. I -- I can't -- I know I've been in latex glove factories. I might have been in a -- a

nitrile glove factory. I can't remember because I haven't been in a glove factory in a while, but it might have been a nitrile glove factory.

Q. What -- what would these audits -- what would an audit of a nitrile glove factory entail, in your professional experience?

A. Well, normally when they're asking us to come in is we're doing a mock FDA QSR/CGMP audit, where we would look at their quality system manual, see how they are -- have they implemented and following it, and looking at their documentation to make sure that the -- all the testing that is required is being done before the products are -- before the products are shipped. So it's a full audit, similar to what an FDA inspector would be doing.

Q. And would -- would that audit involve actually testing gloves or other products for compliance with physical and chemical specifications?

A. Like an FDA investigator, the investigators do not do any testing. All they do is look at what testing the company may be doing and looking at their test results and looking at their documentation. I wouldn't be involved in actually looking at or doing any testing on any of the gloves.

Q. And when you look at documentation, do you

look at the types of, for example, labs that did the testing on the report?

A. Do I -- do I audit the labs or look -- just look at the lab reports?

Q. Well, either?

A. I have been in labs, but I haven't been in a lab -- well, some of the companies have their own labs where they do all their strength tests, elongation tests, pinhole tests. They don't usually do identification tests, though some may have an ASTM -- not an ASTM.

A gas chromatograph for identification of material, but that is very unusual in a -- a glove manufacturer. Normally, if they did any identification test for the biocompatibility, it would be sent out to a recognized lab.

Q. And -- and -- and I guess that was more of my question is, would you look at the reports from such labs that -- that a manufacturer or, you know, an importer would, or a factory would provide to you?

A. Yes, I would look at it. Yes. If -- if -- if -- if it came -- if it was some kind of problem, once the 510(k) is cleared and the company is manufacturing the product, they set up their specifications and their testing requirements before

product release.

So that's what I would be looking at, as an FDA investigator would be looking at it. I -- I was a former FDA investigator, so I'm very familiar with -- with the type of inspections that have to be done.

Q. Would you look at the quality or -- or qualifications of a given lab in connection with such an audit?

A. Well, we would look at -- if they -- well, we would do that during the 510(k). If the lab was doing their final product testing, we would want to see the certification of the lab. We possibly would ask for that to make sure that they qualified their lab to do the testing for them. That would be a GMP and QSR requirement of a -- a vendor qualification.

Q. And in this case, for example, you assisted Kitchen Winners with selecting a lab to do some testing of gloves, correct?

A. That is correct.

Q. And you view a lab, such as ARDL, as a qualified lab to do chemical and physical testing of gloves?

A. Yes. They appear to be qualified.

Q. And we will come back to that. In -- in the fifth bullet point in your CV, you -- you write,

"provided strategic planning, FDA liaison, and documentation review, prepared and/or assisted with over several hundred 510(k)/PMAs."

I just want to make sure, PMA stands for what?

A. Pre-market approval.

Q. And -- and that's the type of clearance that we looked at a few minutes ago, correct?

A. We looked at a 510(k), not a PMA.

Q. Okay. What's the difference?

A. 510(k), you have to show substantially equivalent to a product that's already on the market that already has a 510(k). A PMA, there is no substantially equivalent of your device, and you have to show safety and efficacy. Where a 510(k), you normally have to show comparison between your device and the device that you're substantially equivalent to that already has a 510(k). FDA approves a PMA. FDA clears a 510(k).

Q. And -- and again, is it your testimony that you do not recall providing services with respect to obtaining a 510(k) number for -- well, let me ask, actually, a different question, because I didn't ask you this.

Are you familiar with a company named

Dongguan Grinvald Technology Co., Ltd.?

A. Doesn't sound familiar.

Q. Okay. I mean, are you personally involved with every project that MDI Consultants works on?

A. No.

Q. In your work with FDI Consultants -- MDI Consultants, are you involved with any product labeling?

MR. SPERBER: Objection as to the form.

THE WITNESS: Yeah. We -- we review product labeling, and we have to review product labeling for any 510(k) that we would submit.

BY MR. RAKHUNOV:

Q. Okay. What is the significance of labeling with respect to -- from the FDA perspective with respect to medical devices, such as nitrile gloves?

A. Well, the labeling has to -- there are -- there are specific requirements for medical device labeling. I don't know what the exact 21 CFR number it is, but for medical devices you have to have the -- identify the product that's in the -- in the -- the device that you're marketing, it has to be on the label.

You have to have the amount or number. You have to have if there was any warnings. Like, if there

was -- if there was latex warnings about any allergies, then you have to have a -- the name and address or the -- or how the company could be contacted in case of an emergency. I -- offhand, I think those are the things that you need.

Q. And does the labeling of a particular product have to be consistent with the product code and other -- other six of the 510 number for the device?

A. Repeat that. You broke up. Repeat that, please.

Q. Yeah. So let me -- let me -- let me ask it again. The labeling on medical device, such as nitrile gloves, does it have to be consistent, in your experience, with the product code for which the 510(k) was received?

A. That is correct.

Q. Does someone -- do you -- are you familiar with an individual named Aristotle Nafpliotis?

A. Oh, Aristotle? Yeah. He's my associate.

Q. He's your associate. Okay. How long has Aristotle worked with MDI?

A. I think a little over three years.

MR. RAKHUNOV: Let me -- sending another e-mail, Counsel, with -- so we have Exhibit 1, and we have Exhibit 7. Let's call this Exhibit 8. We will

fill the others in.

(EXHIBIT 8 MARKED FOR IDENTIFICATION)

THE COURT REPORTER: Just for clarity, what -- what would you like to title Exhibit 1?

MR. RAKHUNOV: Expert -- Expert Report. We can do it.

THE COURT REPORTER: Thank you for that. And this next exhibit, Exhibit 8?

MR. RAKHUNOV: Exhibit 8, we can call it June 11th, 2021, Acknowledgement Letter.

THE COURT REPORTER: Thank you, sir.

THE WITNESS: I'm waiting for -- all right. Just came in.

BY MR. RAKHUNOV:

Q. Okay. Great.

A. Okay.

Q. So Mr. Schwartz, once you open up Exhibit 8, please review it and let me know if you recognize the document.

A. Okay. Well, I understand the letter. Yeah.

Q. So what -- what is this letter?

A. This is an acknowledgement letter that the FDA received a 510(k) application by my associate, Aristotle, that we submitted to the FDA in June of 2021. And it was a --

Q. And did --

A. For powder-free nitrile gloves for --

Q. And it's --

A. That we prepared and submitted for Dongguan Grinvald Technology. And sorry, I did not remember that.

Q. No. That -- that's okay. There's no need to apologize. And -- and you see that -- that this acknowledgement letter specifically mentions Medcare powder-free blue nitrile patient examination gloves, correct?

A. That's correct.

Q. And how quickly does an acknowledgement letter like this usually come from the FDA following an application submission?

A. Well, this was during COVID still, so things were pretty crazy. But it -- normally 30 -- about 30 days or so, 30 to 45 days. They want to make sure they have -- that's the first review, and that's just an acknowledgement, and they give it the number. So from then on, that number is supposed to follow that application.

Q. So the -- that number K211808, you know, would that be -- if this product were approved, would that ultimately become the 510(k) number for the

product, subject to this application?

A. If the 510(k) is cleared, yes, not approved.

Q. Cleared, I'm sorry. I --

A. I just want to keep --

Q. I appreciate --

A. I just want to keep it under the same level.

Q. Absolutely. And this acknowledgement letter dated June 11th, 2021, this -- this does not constitute a clearance, correct?

A. That is correct.

Q. All right. And -- and looking at this acknowledgement letter, does this, in any way, refresh your recollection as to the work that MDI did for Grinvald -- Dongguan Grinvald Technology Co.?

A. No. At that time, we were submitting a -- a very large amount of 510(k)s for various companies. That -- that does not refresh my memory.

Q. Do you know -- does this, in any way, refresh your memory as to whether Dongguan Grinvald Technology still a client of MDI to this date?

A. I would have to ask my office manager if we are their U.S. agent or official correspondent. I have -- I would not know offhand.

Q. And as far as the -- and I know this acknowledgement letter doesn't have this type of

information, but does this suggest that your firm would have been the one to submit the application for the clearance for this product?

A. That is correct.

Q. And would that application for clearance identify the -- the predicate device and the bioequivalency standards that the product -- that would apply to the products?

A. That is correct.

Q. And wait, do you see that in -- this particular acknowledgement letter references the word Medcare specifically? Does a 510(k) letter have to specify the brand name of a particular device, for example?

A. We don't recommend it. You can get away with it being --

Q. I'm -- I'm sorry. I just -- I -- I got an e-mail and it cut out your last word. Can you just repeat your answer?

A. It does not have to have a specific brand.

Q. But it has to meet the specific specifications?

A. Correct.

Q. All right. So I -- I believe you said this earlier, but you're not an expert in actually

performing testing on gloves for physical or chemical properties, correct?

A. That is correct.

Q. Okay. And you're not a statistician expert, correct?

A. That is correct.

Q. And -- and you've never been -- you've never been retained as a statistician, correct?

A. Oh, that is correct.

Q. Okay. There's a publication identified under lectures and -- and it's actually the first. And it says, "Seminar on FDA Regulations as They Pertain to the Examination Glove Industry."

A. Are you -- well, I -- I lost you. Where are you looking?

Q. So I'm looking under lectures, seminars, in your CV, and it's the first one that says, "Seminar on FDA Regulations as They Pertain to the Examination Glove Industry."

A. Okay. Let me -- let me find that one. Okay. Got it.

Q. Do you recall what that was -- what that seminar was about?

A. Wow. Well, you see the date on that, right?

Q. I do. I know. And I know it's a long shot,

but I -- I thought I would ask.

A. Well, I'll tell you. Prior to 19 -- prior to 1988, the FDA classified examination gloves as a Class I, which they still are, but they were 510(k) exempt. In 1988, as a result of the HIV crisis and hepatitis, the FDA reclassified examination gloves to need -- to require a 510(k) and that the manufacturing had to follow the GMP.

So the -- the main manufacturing plants of examination gloves was in Taiwan, and we were invited to Taiwan to give a -- a seminar at the Taiwan Glove Association. So I remember this like -- like it was yesterday. And we had 400 -- there was 400 manufacturers involved or -- or members of the Taiwanese Glove Association. And we went to Taipei, and we gave a seminar on the FDA regulation as they pertain to the examination glove industry.

It was a two-day seminar explaining the new rules and regulations that will pertain to them to be able to export these gloves to the United States. And then we were lucky enough to pick up about two dozen clients from that seminar.

Q. Okay. Do you still have any written materials from that seminar -- well, let me actually ask a different question.

In -- in more recent past, have you given any seminars or -- or -- or speeches or taught any classes regarding examination gloves?

A. Probably not specific to examination gloves, unless I was at an examination glove company and I was giving them a -- an introduction to the U.S. regulations, because I do that as part of the training to the staff.

Q. So Mr. Schwartz, did you do anything to prepare for today's deposition?

A. Did I do anything? I took a shower.

Q. Well, we're not in the same room, so I -- I -- I guess that -- I -- I don't even have to say I appreciate that. Did you review any documents to prepare for today?

A. No.

Q. Did you meet with -- and this is just a yes or no answer. Did you meet with Mr. Sperber to prepare for today?

A. Sperber -- did I meet with Sperber? I may -- I might --

Q. And --

A. I -- not today.

Q. Not today. Okay. Did you -- did you have discussions with anyone whatsoever, whether Aristotle

or anyone else, in preparation for today's deposition?

A. Yes.

Q. With who?

A. With an attorney, Meir.

Q. And do you know what firm or office that attorney --

MR. SPERBER: Just -- just -- just for clarity, Meir Goldberg is -- is one of my associates.

MR. RAKHUNOV: Okay. Okay.

BY MR. RAKHUNOV:

Q. That's -- that -- and when did you have a meeting or a conversation with that attorney?

A. Yesterday afternoon.

Q. How long did you meet with the attorney for?

A. About 20 minutes.

Q. Did you have any discussions with someone named Hershey Weiner in preparation for today's deposition?

A. Please clarify. I'm not sure. I -- there was somebody else on the call. I -- I don't recall the name.

MR. SPERBER: Yeah. That would be me.

THE WITNESS: Okay. It was. Okay.

MR. SPERBER: For -- for the record.

MR. RAKHUNOV: Fair enough.

BY MR. RAKHUNOV:

Q. Do you know someone named Joseph or Hershey Weiner?

A. Doesn't sound familiar.

Q. All right. Mr. Schwartz, when were you first contacted about providing expert work for this case?

A. I think it was in December sometime.

Q. In December of --

A. In the -- late December.

Q. Of 2023, correct?

A. That is correct.

Q. Who contacted you?

A. Mr. Goldberg.

Q. Do you know how Mr. Goldberg learned of you or MDI Consultants?

A. I worked with him on a case prior to this.

Q. That was my next question. What -- what case did you work on with Mr. Goldberg?

A. You know what? I -- I would have to refresh my memory. I -- I don't remember cases.

Q. Well, what kind of a case was it? Let's start with that.

A. It was a glove case also, examination.

Q. It was -- was it another case involving

Medcare brand nitrile examination gloves?

A. I don't think so.

Q. Was it -- did it involve LevMed brand gloves?

A. You know what? You're catching me off -- I -- I would have to get back to you. I can get you the exact name. I -- names -- I don't remember the names of my grandkids.

Q. Did you provide -- the other case that you worked with Mr. Sperber's firm on, when did you work on that case?

A. It was the spring, summer, just --

Q. Of -- of 2023?

A. That's correct.

Q. And did you provide any expert testimony in that case?

A. Written.

Q. So you -- you provided a written report?

A. Correct.

Q. Okay. Have you been deposed in that case?

A. Not yet.

Q. Okay. But you -- you expect to be deposed in that case?

A. There's a chance.

Q. Does that case involve a party named Silver

Wing Medical? Does that sound familiar?

A. Again, it might, but I -- I -- I -- I don't want to say yes or no until I look at it. Sorry.

Q. No. That -- that's fine. Is Kitchen Winners a party to that case, that retained you?

A. I don't think so.

Q. What kind of -- of expert advice did you -- or expert opinion did you provide in the other case for Mr. Sperber's firm?

A. That case was involving the quality of the gloves that were being shipped overseas and the -- the -- the possibility of damage to the gloves because of time-related storage.

Q. And what expertise did you lend to that case?

MR. SPERBER: Objection to the form.

THE WITNESS: It was my experience with environmental conditions that might affect the quality of the gloves.

BY MR. RAKHUNOV:

Q. Do you know whether that case is pending in state or federal --

A. I -- not offhand.

Q. Were you providing an expert report in that case as a rebuttal expert or as a -- as an affirmative

expert, if you remember?

A. I -- I -- I don't remember if -- when we -- I'm -- I'm not sure exactly. I would have to go back and look at the report.

Q. Is the case that we just talked about the only other case that you've worked on with Mr. Sperber's law firm?

A. I think Meir hired me a few years, a -- over a year ago on another case. And I can't remember exactly, but it was a -- a case involving gloves.

Q. And did -- were you -- did you give a deposition in that other case?

A. No.

Q. Did you give any testimony other than -- well, did you give a written report in that other case?

A. You know what? I'd have to go back and look. I -- I know I didn't -- we -- we sent gloves out for testing. I can't remember -- I can't remember now whether it was a written report or -- or an opinion page.

Q. So turning back to this engagement, do you know how many hours you spent working on this particular case?

A. This case right now, I -- I would say probably eight -- maybe eight hours.

Q. Let's turn to the beginning of your report. This is -- we're -- we're back to Exhibit 1, and this is Page 4 of the PDF document, and it's titled Alan Schwartz Expert Rebuttal Report. Let me know when you get there.

A. And that goes all the way back. Okay. That was it before. All right. That's, yeah, Exhibit 1. Okay. Let me get to the top. All right.

Q. Okay. So first question, who drafted this report?

A. Let's see. That's my background. Wait a minute. Let me get -- is it the first -- let's see. The report. Exhibit 1 is my -- okay, my rebuttal report. It was drafted -- an -- an original draft was drafted by Mr. Goldberg.

Q. Did you review a draft?

A. Of course.

Q. Okay. Do -- do you recall having substantial edits?

A. There were edits. I don't know if they were substantial, but there were edits.

Q. Was Mr. -- if you -- if it's okay, I'll call him Aristotle. Was Aristotle involved in your -- your work on this case?

A. I think he helped me find the lab, but I

think that was about it.

Q. Do you know what he did to find the lab?

A. I did. He -- I think he did the research of where we could get the lab tested and -- and get it done as fast as possible.

Q. Did he have communications with the lab?

A. Did he have communications?

Q. Yeah.

A. Either he did, or my office manager did.

Q. Do you recall Mr. Sperber asking you to collect your communications with -- or MDIs communications with ARDL lab to be produced in this case?

A. Yes.

Q. Did you ask Aristotle or others in your firm to gather any such communications?

A. I did. I asked my office manager.

Q. All right. So let's -- let's -- let's get -- get into your report. What opinions were you asked to render in this case?

A. Strictly about having the gloves sent to the lab, having them tested, and what the results of the tests were.

Q. Why -- so -- and -- and -- and just take this for what it is, but I'm just trying to understand

why separate expertise was required in order to send -- send gloves to a lab to get tested rather than just, you know, Mr. Sperber hiring a lab directly.

I want to understand what your role is and what expertise you bring to bear to this case?

A. I think you want to ask them, not me.

Q. Well, I -- I do have to ask you. I -- I can't get them under oath, not -- not quite yet.

A. Well, I guess as a former FDA -- involved with gloves and -- and being involved, they wanted to know which lab could get the -- the gloves tested and work with the lab to get it done as fast as possible. We work with a lot of labs. So it's -- it's not unusual that they would ask an expert in the area to do it.

Q. And you're not rendering any opinions here as to whether the testing reflects compliance or non-compliance with any particular FDA specifications or regulations, correct?

A. Well, the test that they wanted done was to determine if it was nitrile gloves. So they wanted the test to determine that they were -- the gloves were made of nitrile. So that's a pretty straightforward test. It's not a -- a test of an ASTM standard for various specifications.

Q. And you're also described as providing a rebuttal report to -- to a report submitted by Dr. Jason Poulton of ARDL, and an expert report of John Carson, statistician. You see that identified in your -- in the second paragraph under Background section?

A. Right. Let's see. I retained -- what's since been identified a testing laboratory. Right. And the rebuttal reports, right. I see that, yes.

Q. Okay. But you're not actually disputing any testing results or conclusions from the testing results provided by Dr. Poulton and ARDL, correct?

A. Correct.

Q. And you're not actually providing any opinion to rebut any statistical issues in Dr. Carson's report, correct?

A. Correct.

Q. So when you write, and we're still in the Paragraph 2, that you were asked to quote, "analyze the results of those tests." What -- what does that mean?

A. Well, they wanted me to just review the test reports of both Dr. Poulton, Dr. Carson, and review the test reports I received from the lab.

Q. Okay. So let -- let's just -- I mean, we -- we can agree that the testing reports that, for example, ARDL provided on whatever gloves that they

tested showed some nitrile content, correct?

A. Correct.

Q. And we can all see that just looking on the face of those reports, correct?

A. Correct.

Q. Okay. What -- what expert opinion did you render to Mr. Sperber and his firm beyond what the reports actually say?

A. Well, the only thing that I -- I -- that I did bring up to them was the amount of gloves that were tested based on the size -- the sample size that was sent to the lab and how that represented the -- the -- the large amount of -- of gloves that were shipped.

Q. Can you explain that?

A. In other words, there was not -- they didn't -- there is a -- a -- the FDA recommends you do a statistical sampling. I'm not a -- a -- an expert in statistical sampling or statistics, but the FDA does have a statistical sample in size to determine -- to be used, that the FDA uses, and they recommend that companies use for testing.

And I just brought up the -- the fact that, you know, the sample size they used did not represent a -- the AQL level that the FDA might ask for in -- in looking at testing of a product.

Q. And when you say, "they used," you're talking about Mr. Sperber, correct?

A. Correct.

Q. So you're not opining that the testing that they did is representative of any particular --

A. Are you -- you mean Mr. Sperber's testing or Mr. Carson's or Mr. Poulton's testing?

Q. Well, that -- that -- and that's what I'm asking you to clarify. It wasn't exactly clear. Whose testing are you referring to when you're just talking about sampling sizes?

A. Well, both. Dr. Carson's testing sample was -- was very small.

Q. And what FDA recommendations are you referring to here?

A. The FDA uses the ASTM -- the -- let's see. According with the sample size, ISO 2859-1.

Q. Can you repeat that a little -- a little slower? Sorry.

A. ISO 2859-1, the standard for sampling.

Q. Are you -- have you implemented ISO 2859-1 in -- in your experience with MDI?

A. For -- for this sampling or in general?

Q. In general?

A. We have used that at times to -- to -- to

pick up samples and to determine the samples that companies use when testing their various products.

Q. And are you giving any opinions with respect to sampling in this case?

A. Well, I -- I just made a -- a -- an opinion as to the sample size that was used by Dr. Carson, that their sample size did not follow the ISO sampling plans.

Q. And -- and -- and this is in Section B, you actually quote Dr. Carson referring to the ISO 2859 standard, correct?

A. Correct.

Q. And then you opine that Dr. Poulton's testing did not meet that standard; is that correct?

A. That is correct.

Q. Okay. And you're not -- and you're simply looking at the two reports side by side and just reading them, correct?

A. Correct.

Q. Have you been asked by Mr. Sperber or his firm to conduct any -- any statistical sampling on the gloves at issue?

A. They did not ask me to do that.

Q. Do you have any opinions as to whether the gloves sampled that are described in Section C and D of

your report, and we'll -- we'll get to those in a moment, comply or do not comply with the FDA ISO 2859-1 sampling procedures?

A. All right. It's not an FDA sampling. ISO is the International Standards Organization. It's not an FDA sampling. The FDA doesn't have a sampling plan. They used to use mill spec standards.

Now the -- the -- basically the world uses the ISO standards for sampling -- sample size. So that's the ISO 2859-1. They didn't ask me to sample -- or what the sample size should be for that standard. They did not ask that.

Q. But you agree that some gloves -- some gloves, and some quantities of gloves, were tested as described in Section C and D of your report, correct?

A. That is correct.

Q. And -- and you're not opining as to whether that sampling meets or doesn't meet the ISO 2859-1 standards, correct?

A. That is correct.

Q. All right. So by the way, if you need -- I know we've been going a little over an hour. If you need a five-minute break, this would be a good time to take one before I jump to the --

A. About how long do you think it will be?

Q. I'm sorry?

A. About how much longer, do you think?

Q. I'm hoping to wrap up in -- in an hour.

A. All right. Let me just take a quick break.

Q. Yeah, that sounds good. Okay. Go ahead.

A. All right. So I'm going to put you on -- I'm going to take a --

THE COURT REPORTER: The time is now 1:25 p.m. We are off the record.

(OFF THE RECORD)

THE COURT REPORTER: The time is now 1:36 p.m. We are back on the record.

BY MR. RAKHUNOV:

Q. During the break, Mr. Schwartz, did you speak with the Counsel?

A. No.

Q. So let's look at the bottom paragraph on Page 1 of your rebuttal report, the one that begins with "on or about April 7th"?

A. Okay. The bottom -- let's see. It's, "on or about April 7th." Oh, what page was that?

Q. It is Page 4 of the PDF of Exhibit 1. That's the first page of your rebuttal report.

A. Okay. Let's see. It's, "on or about 7th of April." On or about April -- April 7th, you said?

Q. Yeah. It's the last paragraph, the bottom paragraph.

A. I got it.

Q. Okay. So turning to the second sentence, and I'll just read it into the record, "Pursuant to the SPA, the defendants procured approximately 55 to 60 containers of gloves, amounting to approximately 1.7 million boxes of gloves." You -- you see that sentence?

A. Yes.

Q. So where did you get the information that the defendants procured approximately 55 to 60 containers of gloves?

A. From the attorneys.

Q. Okay. Did you review any packing slips, invoices, or any documentation to independently verify that statement?

A. I don't think they sent me any documents on that.

Q. Okay. Well, do you have an understanding, in your -- in your industry experience, whether the word container has any significance when it comes to shipping medical devices from China to the U.S.?

A. Yeah. Yes.

Q. What is your understanding?

A. A container is a -- a -- well, they use containers for shipping large volumes of products, and they -- the container could be of various sizes. And they may have -- made of steel containers that are put on ships to sit -- ship them by -- by boat.

Q. Okay. So when you write here, "55 to 60 containers," I mean, are you assuming any particular size? And I'm not asking you to do the math, dividing 1.7 million by that number, but do you have any assumptions as to the types of containers that gloves would be shipped in?

A. No.

Q. Well, let's -- let's go to the next sentence, "I have been informed that the gloves the defendants procured were all manufactured under two different lot numbers - 202103010101 and T4." You see that sentence?

A. Yes.

Q. Okay. Where did you obtain that information from?

A. From the attorneys.

Q. Did you do anything, such as review any documentation, to verify that statement?

A. No.

Q. Okay. Do you have any understanding of what

a lot number means in the context of glove manufacturing?

A. Well, a lot is supplied by a company and it -- it depends on them on what size the lot would be. So a lot number could be one day's production. It could be a -- a purchase order production. So it all depends on the company and how they want to define it.

Q. Do you have any understanding, specifically, as to how the lot numbers were defined for the gloves at issue in this case?

A. No.

Q. In your experience generally, is -- do you have any understanding or opinion as to the significance of gloves sharing the same lot number?

A. Gloves sharing the same lot number. I -- I would have to know more information as to what that means. It -- it all depends on -- on the manufacturer, or the shipper, or what they are using as a lot number and how they're using it.

Q. Okay. And did you obtain any information in this case about what -- you know, what lot numbers signify?

A. No.

Q. Were you asked to make any assumptions by Mr. Sperber, or his firm, as to what these lot numbers

signified?

A. No.

Q. All right. So for the next sentence here, you know, approximately 80 percent of the gloves were manufactured under lot number 202103010101, and 20 percent under lot number T4.

That information, safe to assume, also came from Counsel?

A. Correct.

Q. And you didn't review any documents or any other materials to independently verify the accuracy of that assumption?

A. Correct.

Q. Okay. These lot numbers that are referenced in your report, have you seen any actual glove boxes bearing those lot numbers?

A. No.

Q. In performing your expert work here, did you see any glove boxes, period?

A. No.

Q. Were any glove boxes shipped to MDI in connection with your expert work in this case?

A. No.

Q. Have you ever seen a box of Medcare brand gloves?

A. Not that I can remember.

Q. So if I were to show you on the screen, right now, this box of gloves -- I don't know how well you can see it on your phone.

MR. SPERBER: For the record, it's very blurry.

MR. RAKHUNOV: It is. And I'm hoping -- well, you know what? That's okay. There'll be -- I -- I have an exhibit with some images on it, so we'll handle it that way.

BY MR. RAKHUNOV:

Q. All right. And -- and again, just to be clear, the information about the lot numbers and the percentage allocations came from Counsel or from actual parties?

A. That's correct.

MR. SPERBER: Just -- just could you -- which was the answer? I didn't understand.

MR. RAKHUNOV: Oh. Yeah. Yeah.

BY MR. RAKHUNOV:

Q. So Counsel provided you the information, not somebody at Kitchen winners or Adorama, correct?

A. That is correct.

Q. All right. So flipping to the next page of the report, I understand that first paragraph -- well,

it looks like it at least purports to summarize some of the allegations in this lawsuit.

Did you review any pleadings in this case, like, the complaint, or counterclaim, or any discovery responses?

A. I did not.

Q. So let's turn to Section B, the one titled ARDL's Testing for Rock FinTek.

A. Okay.

Q. Okay. So I -- I -- I think we already covered this, so I'll be brief. But is it fair to say that in Section B, you reviewed the two expert reports that Rock FinTek submitted in this case and just compared them side by side in terms of what the reports say?

A. That's correct.

Q. And if we look at the last paragraph in Section B, the one that begins with, "furthermore," and you say in the second sentence, "Also, as stated above, the gloves procured by Defendants were manufactured under only two lot numbers."

Again, that is an assumption that you make from Counsel, not a fact that you're -- that -- that you're opining it to, correct?

A. Correct.

Q. And in the last sentence, when you write, "I can only speculate that the other lots referenced in Dr. Poulton's report submitted for testing are the lots for gloves that were procured by the other defendants in this action."

Do you see that?

A. Yep.

Q. Do you know who the other defendants are?

A. No.

Q. And you don't know what -- what relative quantity of gloves was sold by other defendants as opposed to Mr. Sperber's clients to Rock FinTek?

A. That's correct.

Q. All right. Let's -- let's turn to Section C, SGS Testing by the Defendants. That's the following page. Let me know when you're there, sir.

A. I'm -- I'm here.

Q. Okay. Great. So from reading your report -- and tell me if I'm -- if I'm reading this correctly.

You or anyone at MDI had no direct involvement with the testing described in Section C, correct?

A. That is correct.

Q. Okay. So you have no personal knowledge, or no one at your firm has personal knowledge, as to the

SGS testing described in this section, correct?

A. Correct.

Q. Okay. And so you write that you have been informed that the gloves were stored at various warehouses operated -- owned and operated by Medline Industries, and that Defendants visited several of those warehouses and obtained samples of some of the gloves being stored there.

Again, that -- you were informed by Counsel, correct?

A. Correct. Correct.

Q. All right. So the -- the last sentence in that paragraph -- second to last says, "Specifically, the defendant submitted 40 samples of gloves, 10 gloves from each of the four largest warehouses, to be tested by SGS-IPS."

How do you know that the gloves came from four of the largest warehouses?

A. This is what I was informed.

Q. And the four bullet points immediately following this paragraph are -- are what?

A. I guess, these are the gloves that -- I guess, those showed which warehouse or where they were taken from, and what the lots were taken, and the date they were taken, except for the second one, which was

stated, Middletown.

Q. And -- and if I told you that -- well, have you reviewed any documentation from Medline showing these gloves in -- in various warehouses?

A. No.

Q. And if I told you that the Middletown, New York warehouse was, in fact, the smallest of the warehouses, would you have any factual basis to disagree with me?

A. No.

Q. And the gloves -- so -- that were tested by SGS, those are the ones that appear in -- in the SGS testing reports attached as Exhibit A to your report; is that correct?

A. I think so, yes.

Q. And the -- you know, the four bullet points that we're looking at right now, you know, it -- it appears those are the labels on the plastic baggies in which the gloves were -- appear in the photographs.

Do you recall reviewing that?

A. Yes.

Q. Okay. So let's just take a look at those four bullet points. Do you see in the latter two, there's a -- a number-letter sequence that begins with WH? The first one is -- let me just read it into the

record. It says, "6-13-23, WH9550DD0300"?

A. Yes.

Q. Okay. And then there's one below it, has the same date of 6-13-23, and it says, "WH9251CC0200." Do you see that?

A. Correct, yes.

Q. Do -- do you know what the WH number-letter sequence refers to in these bullet points?

A. I -- I could only speculate, but I would have no idea if it's true or not. WH usually stands for warehouse, but I'm not sure.

Q. And did -- did you ask Counsel what these numbers stood for?

A. No.

Q. But you were asked to assume that the gloves came from four different warehouses with these labels, correct?

A. That's what I was informed of.

Q. If we look at -- let's -- let's jump to the SGS reports, which -- which should be Exhibit A to your report.

What is SGS Organization?

A. It's a world -- worldwide testing lab.

Q. And -- and just curious. Why did your firm not retain SGS when you were asked to do additional

testing in 2024?

A. Well, we were just looking for a local lab to get it done as fast as possible. Normally, a smaller lab might be able to get stuff done faster. SGS is a huge operation, and very, very bureaucratic, and sometimes it's more difficult to get things done quickly.

Q. But looking at -- and now I'm on Page 9 of the PDF, and it's the -- the -- the page that says, "Page 1 of 10, SGS-IPS Testing." Are you with me?

A. I'm looking at Page 9?

Q. Page 9 of the PDF, and -- and at the top right, it says, "Test report, November 29th, 2023"?

A. Yep.

Q. Okay. "Sample description, four NBR glove samples." Do you see that?

A. Hold on a minute. Four -- let's see. Report of analysis. You're looking at still where it says, "Report of the analysis"?

Q. Yes.

A. Yeah. And it says, "Four NBR glove samples provided"?

Q. Yep.

A. Yeah. Okay.

Q. You -- you would agree with me that nowhere

in that page, or nowhere in the SGS report, is the brand Medcare mentioned? Do you agree with me?

A. I agree with you.

Q. And then if you scroll down to Page 3 of 10 in the top right corner, it's, "Table 1, infrared spectroscopy results"?

A. I got it.

Q. Okay. So the -- the four entries under sample identification seem to be consistent with the four bullet points of the warehouse locations that were -- that were tested, correct?

A. Correct.

Q. Okay. All right. And then we have a few pages of lab results, but I want to direct your attention to Appendix A, Page 9 of 10 of the SGS report.

A. 9 of 10? Hold on.

Q. Yes.

A. 9 of 10 -- 3 of 10. All the way past it. Okay. Hold on.

Q. And actually the last two --

A. 9 of 10.

Q. Yeah. 9 of 10 and 10 of 10 have photographs of, would appear to be, you know, sandwich baggies containing some gloves. And each one has a label that

has Mr. Sperber's law firm name on it.

Do you see that?

A. Yes, I do.

Q. Okay. And -- and do you see that some of the gloves have different color hues to them?

A. I -- I -- maybe I could see a slight different color change, I think, or a slight different color between -- let's see. I think -- let's see. The Figure 1. Figure 2, it just looks like more of them. I don't know if that's a different color. Figure 3 looks like it's a little lighter, and Figure 4 goes back to the original -- goes to the ones that look like 1 and 2. So there might be a slight color change.

Q. Any -- any significance to you as a -- as an FDA expert in the color differences between the gloves?

A. Well, I don't know if that would be an expert -- an FDA expert, but unless I was working in the lab, if that would mean anything to me. I am not sure why there would be a -- a slight difference in the colors. Or the shades, not the colors, and the shades of the blue. They -- they -- I guess, they're all labeled blue nitrile, but I'm not sure.

Q. And do you have -- have you seen any documentation or any evidence whatsoever to -- that -- that would confirm that these gloves in these plastic

baggies are Medcare gloves, or what they are at all?

A. Well, I --

MR. SPERBER: Object to the form.

THE WITNESS: No. I -- I couldn't make that determination.

BY MR. RAKHUNOV:

Q. And were you provided any communications between Mr. Sperber's firm and SGS when you were -- when you were asked to put together your expert report here?

A. Only this information that was given to me.

Q. And if -- okay. Well, let's -- it's been a couple of hours, so I forget now exactly which exhibits I've e-mailed out. So let me just take a look --

A. I -- I got Exhibit 1. I got Exhibit 2. I got Exhibit 3, and I got Exhibit 7.

MR. RAKHUNOV: Right. So let's -- let's open Exhibit 3.

(EXHIBIT 3 MARKED FOR IDENTIFICATION)

THE WITNESS: I have it open. Yeah.

BY MR. RAKHUNOV:

Q. Okay. And so do you see this is a four-page document that has some photographs of cartons and boxes of gloves. And take a look at the very first photograph.

Do you see it depicts a -- a white piece of paper taped to some cartons, and it has a number starting with WH on it? Do you see that?

A. I do.

Q. Okay. And just under that is a glove of Medcare that -- that says "Medcare" on it. Do you see that?

A. Yes.

Q. So this is a little more clear than what I was trying to show you.

Is this the first time that you're seeing an actual box of Medcare gloves in connection with your work on this case?

A. I think so.

Q. And do you see right under that, there's a picture with an enlarged side of the box, and it says, "Lot HFK202103010101"? Do you see that?

A. Yes.

Q. Looking at a lot number actually on a box of gloves, does that give you any more information about the significance of what that lot number means in this context?

A. Well, no. That -- that lot number appears to be assigned to that -- that box of gloves. And then it determine -- you know, that was their lot number

that they assigned it. That -- that's all that I would be able to determine on that. It looks like it was manufactured on a date and I -- you know, as an FDA investigator, it looks like it's 2021, March. March 1st of 2021, but I -- I couldn't determine any more.

If you look underneath, it says, "2021.3," so it looks like -- that build date -- is a manufacturer. It looks like it was built -- it was manufactured in March of 2021, and it looks like time runs out on this in February of 2024.

Q. And that little white building symbol, is that a standard symbol used in -- an -- an industry standard symbol used for manufacture date?

A. Yes. It would be, yeah.

Q. Okay. Now, if two boxes of gloves shared this particular lot number, having now looked at the box of gloves, does that tell you anything about what those boxes may have in common?

A. Well, they should have been manufactured in the same lot. That -- like I said, that lot could represent a lot of different things depending on the manufacturer. So could have been a -- a run, a production run, which could take several days. It could be an hour. It could be one day. It -- it -- you know, it -- it all depends what the last digits on

that -- that lot code is. It -- it -- we don't know exactly what it means.

Q. Is it -- is it reasonable to assume that gloves manufactured in the same lot, under the same lot number, would be manufactured under the -- at -- at the same factory?

A. Oh, yes.

Q. Okay. And would it be reasonable to assume that gloves manufactured under the same lot number were manufactured under the same specifications?

A. Yes. It should be, yes. It's expected.

Q. Okay. So -- and then scrolling down to the last two photos on this page, the same thing. We see another label with a WH number, and another photograph of a box of gloves.

This one has a different style lot number that says, "20201106." Do you see that?

A. Yes, I do.

Q. Okay. And then here, that would appear to refer to a November 6th, 2020, manufacturer date, correct?

A. That appears to be the date of it.

Q. And this one has a size on it, and then a three-year later expiration date, correct?

A. Correct.

Q. And if I told you that the two white slips in the photographs in Exhibit 3 represent a pallet location number in the same warehouse in Grayslake, Illinois, would you have any factual basis on which to disagree with that statement?

A. I would have no factual basis for that.

Q. And in connection with your work in this case, you reviewed Dr. Jason Poulton's expert report, correct?

A. Correct.

Q. The two lot numbers that are in Exhibit 3, do you recall seeing those lot numbers identified as part of -- as -- as the lot numbers that Dr. Poulton had tested at ARDL?

A. I would have to go back and look at it. I can't tell offhand.

MR. RAKHUNOV: No. And I -- I appreciate that. And -- and, you know what? Let's -- let's do that. And I don't believe I sent that one over yet, so let me -- let me do that right now.

So I just sent it to Mr. Sperber. So hopefully you have it in a few minutes.

MR. SPERBER: Not yet. I'm -- I'm waiting.

MR. RAKHUNOV: Okay.

MR. SPERBER: I uploaded your --

THE COURT REPORTER: Apologies. Is this Exhibit 4?

MR. SPERBER: Your exhibit.

MR. RAKHUNOV: Yes.

THE COURT REPORTER: And what --

THE WITNESS: Still waiting for it to come.

THE COURT REPORTER: What would you like to label this exhibit?

MR. RAKHUNOV: This one is a little bit bigger in size, so it'll take a second.

So this -- I guess, off the record while you're loading that.

(OFF THE RECORD)

MR. RAKHUNOV: Okay. All right. We can go back on.

So Exhibit 4 is -- it's a 92-page document, and -- and I will represent to you it's the complete, final, expert report that was submitted by Dr. Poulton in this case.

(EXHIBIT 4 MARKED FOR IDENTIFICATION)

BY MR. RAKHUNOV:

Q. And -- and you're welcome to look through as much of this document as you need to. And I will direct your attention to Page 3 at first.

A. Okay. I'm on Page 3.

Q. Okay. And you see a table in the middle of Page 3 that has a -- a number. It -- it has samples and lot numbers in that column. Do you see that?

A. Yep.

Q. And two of the lot numbers are -- and I'm looking at sample 15 and then sample 25 are the lot numbers that we just saw on the sides of boxes in Exhibit 3, correct? You can compare the two if you need to.

A. Give me a chance here. Let's see. Let's see. 0300, 1106. 1106 is the 15 and -- and you're saying 25 of -- of 0101. Let me just check that, 0101. 0101. Yeah. That looks like -- yeah. Those two, yes.

Q. And then if you could please turn to PDF Page 45 of Exhibit 4.

A. 45. Okay.

Q. We need to zoom in a little bit.

A. Okay. I'm in 45.

Q. Okay. And do you see that there's an actual image on this -- on -- on this expert report of a box of gloves bearing lot number HFK, the -- the 3010101?

A. I see the number. It's very hard. Even when I'm enlarging, it doesn't look very good, but if that's what they typed there, I will assume, but I'm not supposed to. Let me see if I can enlarge it any

more. That they took it from the box, let me see. I made it very --

Q. Well, that's okay. You -- you are absolutely entitled to assume things as long as it's clear on the record. So let me just ask you to assume that the gloves that were tested by Dr. Poulton, as reflected on Page 3 of his report, were in fact pulled out of the boxes bearing the lot numbers that we saw in Exhibit 3.

Can you make that assumption?

A. If that -- if that -- well, I could assume that, but if that's what it says -- I mean, I wasn't there to see what he did, but if that's what he's attesting to, I guess, that's what he did.

Q. Okay. So -- and if that's what he did, and the total nitrogen levels in those two lots are non-detectable, you would have no -- no basis to disagree with that, or do you? This is --

A. You mean nitrile. Nitrogen or nitrile?

Q. Nitrile. I -- I apologize. Nitrile. Thank you.

A. I didn't know what nitrogen was, but all right. If that's what he pulled out and tested, then I would have nothing to say on it one way or the other.

Q. And you would expect that those test results

would be consistent across a particular lot number of gloves?

A. I could not assume that. I would have to see how large the lot was, and how many days it might have crossed over, or something else. I mean, I -- I would have to go into the plant and see how the plant was operating, and if there was any chance of cross contamination, or mix-up, or something like that. So there could be a lot of reasons why one box might have had something that didn't test for nitrile, but I cannot attest to that now.

Q. Okay. And -- and I'm not asking you -- I understand that's outside of your opinions here, but I -- I am asking you as far -- that it would be consistent with your expectations that gloves in the same lot number would be manufactured to the same specifications, correct?

A. That is -- that is an assumption I would make, yes.

Q. So and -- and -- all right. So let -- let's -- let's go back to Exhibit 1, your expert report. And I'm sorry, we're jumping around it's just the nature of this.

And -- and I'll ask you to go back to the body of your report in --

A. I'm on --

Q. -- the section -- Section D.

A. Okay. D, yes. Got it.

Q. Well, it -- well and before actually I go there, so the second -- the last sentence of Section C says, "The SGS report confirmed that nitrile was detected in each of the gloves that were tested." Do you see that?

A. Yes.

Q. And again, based on the information that you were provided, you have absolutely no way of knowing that the gloves that the SGS report refers to were in fact MedCare brand gloves that were sold to Rock FinTek that -- in the events underlying this lawsuit, correct?

A. Correct.

Q. So turning to Section D, now this section reflects the testing that MDI ordered to have performed, correct?

A. Correct.

Q. All right. So first sentence, "On or about January 12th, 2024, I received from defendants a total of 150 gloves in varying sizes and from various warehouse for testing analysis and reporting."

How did you receive those gloves?

A. In plastic bags.

Q. And what were the plastic bags contained in? Were they in a box and -- if you recall how they actually arrived?

A. I don't remember.

Q. And I see that you -- again, in your -- Section D of your report, similar to SGS, you don't actually describe the gloves by brand name, including MedCare, correct?

A. Correct.

Q. That's because you didn't know what brand name they were, correct?

A. Correct.

Q. You didn't care, it wasn't a part of your work, correct?

A. Correct.

Q. And -- and the gloves came by mail?

A. Correct.

Q. And did they come from Mr. Sperber's firm or from somewhere else?

A. Sperber's firm.

Q. How -- how do you know that it was 150 gloves? Did somebody actually count them or were you just, again, relying on Mr. Sperber to give you the -- the numbers?

A. We didn't count them. It was based on the

numbers that was on the bags.

Q. And again, there are three bullet points now in Section D, the -- 80 of the gloves were taken from one lot number, 20 of the gloves from another lot number.

You are relying on the labels on the bags for that information, correct?

A. That is correct.

Q. And I'm going to ask you about bullet point 3.

You -- you -- there -- you write here, "50 of the gloves were taken from various lot numbers," the lot numbers are identified in parentheses, "five of which were randomly selected for testing and reporting." Do you see that?

A. Yes.

Q. So why did you test gloves from other lot numbers if -- if the assumption you were asked to make was that all gloves at issue came from the two lot numbers in the first two bullet points?

A. They asked me to run the test. I ran the test.

Q. Okay. And they could have just gone directly to ARDL for this testing, correct?

A. That is correct.

Q. Did Mr. Sperber, or anyone at his firm, ask you to have the gloves, the various gloves, combined together before doing the -- sending them out for testing, if you understand?

A. Yeah. I'm not sure, but I don't recall if that came up.

Q. Do you recall asking ARDL to -- to combine the gloves from multiple boxes together and to test them as one composite sample?

A. I asked them if they could do that.

Q. Okay. Why? Why did you ask them if they could do that?

A. Well, first of all, if the test would be accurate. Normally what happens when you do that, if it does -- if -- if you find one negative, you might not know which lot number it is. I -- I mean, say you find one that is not the -- what you're looking for in the results or would it affect the results. So sometimes it's basically to save time and money, right?

Q. Yeah. But what --

A. By -- by putting all this together.

Q. Well, wouldn't that affect the accuracy of the testing?

A. Well, that's what I wanted to know. If it would affect the accuracy if you -- if you combine 10

gloves and one is not -- one is adulterated, meaning not the actual material, would that be covered by the -- by the other gloves? So you want to make sure that that's not going to happen.

Q. I'm so -- and I'm sorry. I don't fully understand that answer.

So if we have 10 different gloves and -- doesn't it make sense to test the 10 separate gloves to see if any particular, for example, lot number is coming up with different results from others, rather than just mix them all together?

A. Well, when you are using a gas -- what -- they used a -- an ASTM method and they use the infrared spectrophotometer. I think the -- these give off some wavelengths. And if it's the -- and they're -- it's like a fingerprint. So if it gives off a wavelength, say nitrile has a special wavelength and say there was not nitrile, then it would also give off a different wavelength.

So it would show that something was adulterated or -- or something was coming up that was not the nitrile. So you might be able to do all the -- all the gloves at one time to see if they are all of the same ingredients.

Q. I think I understand. And -- and -- and do

you recall what I -- what ARDL told your firm about that request?

A. Right now, I don't remember offhand.

Q. Okay. Why -- and -- and so what is the benefit to combine -- if any, to combining different gloves for testing as opposed to testing multiple individual gloves?

A. Well, it would save money. A lot of companies will do that if they could get away and do that and still get the results that would be accurate for the -- for the -- for the testing that they're looking for.

Q. Okay. And was that proposal something that was requested of you by Mr. Sperber's firm or something that you suggested in order to save money on the testing?

A. It would probably be something I suggested if they wanted to do bulk testing.

MR. RAKHUNOV: Got it.

So if you look at Exhibit 6, which hopefully you have by now.

(EXHIBIT 6 MARKED FOR IDENTIFICATION)

THE WITNESS: Yep. Exhibit -- Exhibit 6. Oh, hold on.

BY MR. RAKHUNOV:

Q. Yes. It's a -- it is a new one.

Hold on. Give me a minute.

THE COURT REPORTER: And what would you like to label this exhibit?

MR. RAKHUNOV: ARDL communications will be fine.

THE COURT REPORTER: Thank you. And what was Exhibit number 5, if I may?

MR. RAKHUNOV: There was not -- I -- I decided to not use it. That -- that is the one limitation of these Zoom depos. It's a little -- takes a little more work to renumber things, if you go out of order and it's different from what you expected. But we can always clean it up in the transcript.

THE COURT REPORTER: Not a problem

THE WITNESS: All right. I got you.

THE COURT REPORTER: Thank you.

THE WITNESS: Opening it up.

BY MR. RAKHUNOV:

Q. Okay. So it's --

A. I got --

Q. Yeah. A Seven-page -- seven-page document, sir. And I -- I will tell you these were provided to us by Dr. Poulton at ARDL.

And so do you see the first page is --

A. Yep.

Q. -- submission by Aristotle and the description of requested services is -- it -- it -- the last line of that is, "Is it possible to combine gloves from multiple boxes together and test them as one composite sample for polymer identification?" Do you see that?

A. Yep. Yeah, sorry.

Q. All right. So that -- go ahead.

A. Yes.

Q. By the way when -- when your firm reached out to ARDL for testing, did anyone advise ARDL that this testing was being conducted for litigation purposes?

A. No.

Q. Do you know whether that would have made a difference in the way that ARDL approached its testing in this matter?

A. It shouldn't.

Q. Or at least any protocols prior to doing the testing, do you -- do you know that one way or another?

A. Well, I'm not familiar with the -- with their protocols. I would suspect it shouldn't, but they might have some internal protocols. But I'm not sure.

Q. And you did not ask ARDL to serve as an expert in this matter, right, just to test some gloves?

A. Correct.

Q. At the time that your firm submitted these requests to ARDL, did you know that Rock FinTek had already hired ARDL and Dr. Poulton to serve as an expert in this case?

A. No. We found that -- that -- that was a coincidence after we saw the other testing there.

Q. All right. So I want to direct your attention to Page 5. And this is an e-mail from Ana Barbur, A-N-A, B-A-R-B-U-R, dated January 9th, 2024, back to Aristotle. And she writes, "Hello, Aristotle. Incorrect polymer ID is a serious problem across the medical PPE market intensely discussed at our ASTM rubber group meetings/medical gloves subcommittee level. BTW, FDA reps were present there as well."

Have you, as an FDA consultant, ever -- are -- are you familiar, as an FDA consultant, an expert, in incorrect polymer ID being a serious problem across the medical PPE market?

A. I have not heard that specifically, no.

Q. And in the second part of the paragraph, Ms. Barbur writes, "Please try to explain to your customer that running a composite sample is simply useless and

potentially harmful to the end users in the healthcare industry." Do you see that?

A. I do see that.

Q. Okay. Do you have any basis to disagree with Ms. Barbur's statement about that?

A. I would not have any way to dispute it.

Q. Okay. And in any event, following this e-mail exchange, the gloves were tested in the way that ARDL suggested they should be tested, individually, correct?

A. Correct.

Q. Probably cost a little bit more to do, correct?

A. Correct.

Q. And again, you have absolutely no idea whatsoever where the gloves that you were -- that you were asked to submit to ARDL came from, correct?

A. That is correct.

Q. And again, beyond simply delivering the results of the testing on whatever these gloves were by ARDL, you're not providing any additional expert explanation or analysis regarding the results of the nitrile testing, correct?

A. That is correct.

Q. So if we were to assume, just for the sake

of assumption however, that the gloves that you had tested and the gloves that SGS had tested were -- they -- let's assume they were in fact gloves that came from MedCare boxes that were associated with the lot numbers set forth in your report.

What would be the significance of -- of such test results in your opinion, if you have one?

A. Repeat the question?

Q. Yeah. So let's -- so first, let's assume that the -- the testing you described, that you relay in your rebuttal report, let's assume that those gloves in fact were MedCare gloves that came from, you know, some of the boxes at -- at issue in this lawsuit, okay. And let's assume that the tests for those gloves were -- had detectable levels of nitrogen as -- that the test attached to your rebuttal reports reflect.

What would be the significance of such testing results?

A. Well, first of all, it's nitrile not nitrogen.

Q. I'm sorry. I keep using that word interchangeably. Nitrile. Okay.

A. Okay. No. If they tested the nitrile and that's what showed up, then I would suspect that the main ingredient that the gloves were made from was

nitrile.

Q. Okay. And -- and how would you extrapolate that to the other gloves in this case?

A. I'm not sure what you mean.

Q. Yeah. So -- so and -- and you would -- would you extend that opinion beyond the actual gloves that were tested?

A. If it came from a lot, that was -- if it came from a lot that was manufactured and that had the lot -- had the nitrile and the test showed nitrile, I would assume that the rest of the gloves in the lot were made of nitrile.

Q. And how many years have you been in the industry, involved in helping manufacturers and importers bring nitrile and other types of medical gloves into the United States?

A. Well, I guess it started in -- 1989 is when latex -- when -- when the FDA changed the regulations on examination gloves. Nitrile gloves didn't come into effect until sometime in the '90s, I don't know exactly when. Because of the latex problems, people went to nitrile.

Q. Did you --

A. But I -- I saw -- the gloves --

Q. I'm sorry.

A. Gloves were back in 1988, 1989 when we worked -- when the FDA changed the regulations.

Q. So the assumptions that you -- you just described about lot numbers are based on decades of experience in the industry, fair to say?

A. Fair to say.

Q. Just a minute. I think we're very close to -- oh, okay.

So let's we -- we can close out of that exhibit and -- and go back -- just briefly back to your CV in Exhibit 1?

A. That's at the bottom of the 1, right? No. That was at the top.

Q. At the bottom. Yes, sir. At the bottom.

A. Okay. Hold on.

Q. And -- and -- and I will -- actually let's --

A. Okay. I'm there again.

Q. Great. So let's turn to your expert witness cases.

A. Okay.

Q. On Page 2 of your CV?

A. Okay.

Q. So one -- I just want to run through these and -- and ask a couple of questions.

So the first listing is an expert witness report under NDA, it just means it's under a confidentiality agreement?

A. Correct.

Q. And it -- it's a patent infringement case, taped deposition. Do you know where that case is pending, what court?

A. Expert witness taped deposition. Let me -- well, the company is in Pennsylvania, so I think it was in Pennsylvania. I'm not sure. That's no -- 2018, right?

Q. No. I'm looking at the very first one, expert witness report under NDA?

A. Oh, patent case.

Q. Yes.

A. That was in 2021. That was out of New York.

Q. Okay. And is that case -- have -- I understand there's a confidentiality agreement, so let's just try yes or no.

Did that case have anything to do with gloves?

A. No.

Q. Okay. The -- the 2019, testified in a partnership case, expert for the company, Respire Medical Inc., Brooklyn, New York.

What did that -- what did test -- your testimony in that case involved?

A. It was -- my expertise was in manufacturing processes and quality control and -- and there was a partnership dispute and just wanted to make sure on who was in charge of what was going on at the time.

Q. Anything to do with gloves?

A. No.

Q. 2018 expert witness in Macario Vazquez v. Brookdale Senior Living case. What did that case involve?

A. I think that was a scooter -- a scooter that went on fire.

Q. Oh, okay. Do you know what court that -- that case was in?

A. I think -- well, I know the company is in Pennsylvania, so I'm not sure if it was -- where -- where the company was defending it or where the -- where the -- where they took law -- did the lawsuit, I'm not sure.

Q. So let's see. The 2017 Hologic case. What did that involve?

A. That was an injury case with a medical device. And I think I -- that was taped in New York. I -- I'm not sure. I -- I -- definitely wasn't a New

York case. I think it was either Texas or Arizona.

Q. Okay. Anything to do with gloves?

A. No.

Q. 1997 GMP expert witness deposition, Becton Dickinson. What did that have to do with?

A. Not gloves. That was test tubes.

Q. So I know earlier today I asked you about some cases that you're involved with that do have something to do with gloves, and I understand you have not been deposed in those cases.

Have you ever given any testimony at deposition or at trial in any case having to do with medical gloves?

A. No.

Q. Okay. I guess until today?

A. Yeah. And I'll add it to the list.

Q. And do you -- other than what we discussed, what I've asked you about and what's set forth in your rebuttal report, are you going to testify as to any other expert opinions in this case?

A. Not that I know of.

Q. Okay. Other than what we've discussed today and what's set forth in your report, do you have any additional rebuttals to the expert reports of either Dr. Carson or Dr. Poulton?

A. Not at this time.

MR. RAKHUNOV: Okay. So I -- I believe that I'm done. I'm not sure if Mr. Sperber has anything.

MR. SPERBER: I -- I just have -- I just have one question to clarify something.

MR. RAKHUNOV: Okay. If -- and then I -- and then actually, if you don't mind, I'll take just one minute to run through my notes to make sure I didn't forget something before we wrap it up.

MR. SPERBER: Do you -- do you want to do that first or should I ask my one question?

MR. RAKHUNOV: It's up -- it's up to you. It might be more efficient for you to just go ahead with your question while I --

MR. SPERBER: Okay. Sure. Sure.

EXAMINATION

BY MR. SPERBER:

Q. So Mr. Schwartz, you mentioned earlier that the -- the gloves that you sent to ARDL for testing and this matter came from my office.

Is -- is it possible if they were sent to your office directly from the client in this matter and not from my office?

A. It -- it is possible. I -- I wasn't in the office when they opened it up, so I would have to check

with my office. I'm sorry.

MR. SPERBER: Okay. Thank you.

MR. RAKHUNOV: Great.

EXAMINATION

BY MR. RAKHUNOV:

Q. And regardless of who sent them to you, they came in plastic baggies with no -- and not in boxes or -- or otherwise -- well, they came in plastic baggies and not in actual boxes of gloves, correct?

A. That's correct.

MR. RAKHUNOV: I -- you know, it probably makes sense for me to just go off-screen for a second. Let's just take one minute, and I think we're done.

THE COURT REPORTER: Would you like to stay on record, or would you like to go off one minute?

MR. RAKHUNOV: Up to you.

THE COURT REPORTER: Okay. Off the record, 2:35 p.m.

(OFF THE RECORD)

THE COURT REPORTER: Back on the record, 2:36 p.m.

MR. RAKHUNOV: Mr. Schwartz, thank you for your time. I have nothing further and have a -- have a great day.

THE WITNESS: Thank you. Bye now.

MR. SPERBER: Thank you very much.

THE COURT REPORTER: And would you like a regular delivery of the transcript?

MR. RAKHUNOV: Regular is fine, and we just need electronic.

THE COURT REPORTER: Okay. Any copies today?

MR. SPERBER: Same on -- same on my end. I'll take an E-tran, electronic version.

THE COURT REPORTER: Okay. Is that a separate order or -- or you'll be receiving from --

MR. SPERBER: I guess we'll be receiving that as -- as the counsel for the deponent.

THE COURT REPORTER: You got it.

Okay. That ends the deposition today. The time is 2:36 p.m. We are off the record.

(DEPOSITION CONCLUDED AT 2:36 P.M.)

REPORTER'S CERTIFICATE

I, JOHN SHEFFIELD, a Court Reporter and Notary Public in and for the State of New York, do hereby certify:

That ALAN SCHWARTZ, the witness whose examination is hereinbefore set forth, was first duly sworn by me and that this transcript of said testimony is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 13th day of February, 2024.

_____

JOHN SHEFFIELD
Court Reporter and Notary Public
Notary Commission New York/01SH6435698
Commission Expires: July 5, 2026

DEPOSITION ERRATA SHEET

Our Assignment No. 00048635
Case Caption: ROCK FINTEK LLC v. KITCHEN WINNERS NY INC. ET AL.

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my deposition taken in the above-captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the _____ day of _____, 2024.

_____

ALAN SCHWARTZ

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ALAN SCHWARTZ

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ALAN SCHWARTZ